(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 1 September 2005 (01.09.2005)

PCT

(10) International Publication Number WO 2005/080329 A2

(51) International Patent Classification⁷: C07D 209/00

(21) International Application Number:

PCT/IN2005/000056

(22) International Filing Date: 22 February 2005 (22.02.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

219/MUM/2004 23 February 2004 (23.02.2004) IN

(71) Applicant (for all designated States except US): CADILA HEALTHCAR LIMITED [IN/IN]; Zydus Tower, Satellite Corss Roads, Ahmedabad 380 015, Gujarat (IN).

(72) Inventors; and

- (75) Inventors/Applicants (for US only): SHAH, Dhiraj, R. [IN/IN]; Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads, Ahmedabad 380 015, Gujarat (IN). NAIK, Ashish, P. [IN/IN]; Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads, Ahmedabad 380 015, Gujarat (IN). PUROHIT, Parva, Y. [IN/IN]; Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads, Ahmedabad 380 015, Gujarat (IN). SHARMA, Rajivkumar [IN/IN]; Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads, Ahmedabad 380 015, Gujarat (IN). AGARWAL, Virendra, Kumar [IN/IN]; Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads, Ahmedabad 380 015, Gujarat (IN).
- (74) Agents: SUBRAMANIAM, Hariharan et al.; Subramaniam, Nataraj & Associates, E-556, Greater Kailash II, New Delhi 110 048 (IN).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,

CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

Published:

 without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PROCESS FOR MANUFACTURE OF RACEMIC CARVEDILOL

(57) **Abstract:** The invention relates to a novel process for the manufacture of Carvedilol of high HPLC purity (>99.5 %) having individual impurity less than 0.1 %. The product is isolated from reaction mass as a salt with suitable organic acids which on further purification is converted into the free base *i.e.*, Carvedilol.

